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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,356	01/26/2004	Paul Reid	1013-3	8100

7590 04/07/2005

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,356	REID ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004 and 18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *1-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SUPPLEMENTAL DETAILED ACTION

Miscellaneous Communication

1. The following action is a supplemental office action. The instant office action replaces the office action having an approximate mailing date of March 22, 2005. The difference between the instant action and that previous mailed is the inclusion of prior art and double patenting rejection, both of which as inadvertently omitted from the previous office action.

Election/Restrictions

2. Applicant's election without traverse of Group I, HIV, in the reply filed on 01/18/2005 is acknowledged. Applicant's amendment to the claims to reflect Applicant's election is also noted.

Status of Claims

3. Claims 1-15 are pending and under examination.

Sequence Compliance

4. This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. A sequence identifier is not attached to disclosed sequences, a CRF submission is not provided, nor is a sequence listing provided. Applicant's response to this office action must includes appropriate action(s) that would place the application in compliance with 37 CFR 1.821(a)(1) and (a)(2); otherwise the response will be treated as non-responsive.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g., line 20 of page 5 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. The abstract of the disclosure is objected to because it contains an incomplete sentence, line 10 of page 41 of the specification. Correction is required. See MPEP § 608.01(b).

Claim Objections

7. Claims 1-15 are objected to because of the following informalities: As written, the claim reads on a method of dealing of, treatment of, animals that are suffering from retroviral infections; not a method of treating retroviral infections in animals that are diagnosed with retroviral infectivity. Additionally, the claims are objected to for the recitation "modified" with detoxified. With the use of "detoxified", it is abundantly clear that the venom has been modified. Ergo, the use of "modified" in the claims is considered redundant.

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim requires the method of claim 1 to further comprise a viral condition. The method of claim 1 all ready requires that the animal to have a retroviral infection. Appropriate correction is required

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5-11 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 5 and 7 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 5 recites the limitation "modified cobratoxin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Mundschenk et al. (WO 01/70173, published 09-2001).

Claims 1-4 are directed to a method of providing treatment to animals suffering from retroviral infection comprising the administration of an effective amount of a detoxified modified venom composition containing alpha-neurotoxins to the animal. The

claims require that the composition comprises a fraction of the whole venom containing the alpha-neurotoxins; and the toxin to cobratoxin or be selected from the group consisting of alpha-bungarotoxin, alpha-cobratoxin, alpha-cobrotoxin, alpha-conotoxins (g1, M1, S1, S1A, Iml), alpha-dendrotoxin and erabutoxin.

Mundschenk et al. teaches a method of providing treatment to animals suffering from retroviral infection comprising the administration of an effective amount of a detoxified modified venom composition containing alpha-neurotoxins to the animal. [Line 25 of page 44-line 5 of page 49.] The composition Mundschenk et al. used comprises a fraction of the whole venom containing the alpha-neurotoxins, specifically detoxified alpha-cobratoxin. [Lines 1-25 of page 40.] Mundschenk et al. teaches the claimed invention. Ergo, Mundschenk et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (WO 01/70173, published 09-2001) as applied to claim 1 above, in view of Sanders et al. (U.S Patent No. 3888977).

Claims 5-6 limit the dose amount to.01 to 10 ml or .2 to 2ml of the composition per 150 lbs of body weight, when administered to a human, based on a .1% solution of the detoxified cobratoxin, which is an alpha-neurotoxin.

The significance of Mundschenk et al. is discussed above.

Mundschenk et al. does not teach the administration of .01 to 10 ml or .2 to 2ml of the composition to a human per 150 lbs of body weight, based on a .1% solution of the detoxified cobratoxin.

However, Sanders et al. (U.S Patent No. 3888977) teaches the normal dose to administer is .05 to 10 ml and .7 to 2ml of the composition to a human per 150 lbs of body weight, based on a .1% solution of the modified cobratoxin. [Lines 24-52, column 6.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer .05 to 10 ml and .7 to 2ml of the composition to a human per 150 lbs of body weight, based on a .1% solution of the modified cobratoxin to a patient. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the dose amount is art recognized as the normal dose amount; furthermore, Applicant has not demonstrated that the claimed amount yields unexpected results.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

14. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (WO 01/70173, published 09-2001) and Sanders et al., as applied to claims 1 and 5 above.

The claims require the composition be administered with the frequency of every other week to daily, at least weekly, and at least daily.

Sanders et al. suggests that administration takes place every other week, at least weekly, and every other day or daily. [Lines 24-52, column 6.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition every other week, at least weekly, and every other day or daily. One of ordinary skill in the art at the time the invention was made would have been motivated to administer the composition every other week, at least weekly, and every other day or daily to a patient to optimize the treatment protocol. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the claimed treatment schedule is well known in the art; furthermore, Applicant has not demonstrated that the claimed treatment schedule yields unexpected results.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

15. Claims 10-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (WO 01/70173, published 09-2001) and Sanders et al., as applied to claims 1 and 5 above.

Claim 10 requires the mode of administration to be selected from the group consisting of injection, orally, optically and by intradermal routes. Claim 11 further limits injection to subcutaneous, intramuscular, or intravenous. Claim 14 requires the administration of benzalkonium chloride with the alpha-cobratoxin, when administered orally.

In addition to the discussion provided above for the teaching of Mundschenk et al. and Sanders et al.; it is noted that the detoxified composition of Mundschenk et al. also contains benzalkonium chloride. [Lines 30-31 of page 42.]

Additionally, Sanders et al. teaches that the detoxified venom composition can be administered orally, subcutaneously, intramuscularly, intramuscularly and intravenously. [Lines 24-50, column 6.] Like Sanders et al., Mundschenk et al. also teaches that the detoxified venom composition can be administered by any number of routes including, subcutaneous, intramuscular, oral, intravenous, intradermal and intranasal. [Lines 14-20 of page 23.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition via injection, orally, and by intradermal routes. One of ordinary skill in the art at the time the invention was made would have been motivated to use the known method of administration to an animal to facilitate the administration of the detoxified venom composition.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success because the claimed modes of administration are well known in the art.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (WO 01/70173, published 09-2001) as applied to claim 1 above.

Mundschenk et al. does not teach the administration of the detoxified venom composition to an animal suffering from HIV infectivity. However, Mundschenk et al. suggests the use of the composition to treat animals that suffers from HIV infectivity. [Lines 30-33 of page 22.]

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the detoxified venom composition to an animal that suffers from HIV infectivity. One of ordinary skill in the art at the time the invention was made would have been motivated to administer the composition to an animal that suffers from HIV to treat the animal of HIV infectivity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Mundschenk et al. teaches that the detoxified venom composition inhibits HIV infectivity. [Line 5 of page 49-lines 21 of page 53.]

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

17. Claim 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (WO 01/70173, published 09-2001) and Sanders et al., as applied to claims 1, 5 and 10 above, in further view of Pietras et al. (U.S. Patent No. 6306832).

Claim 15 requires the administration of benzalkonium chloride with the alpha-cobratoxin, wherein the cobratoxin to benzalkonium chloride ratio is between 1:6 to 1:8, and 1:7.5,when administered orally.

Mundschenk et al. and Sanders et al. do not teach the claimed ratio. However, Pietras et al. teaches the use of benzalkonium chloride as a preservative. It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to adjust the ratios. One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the ratios to optimize the shelf life of the composition without compromising the immunogenic affect rendered by the composition. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for optimizing the ratios because it is part of routine experimentation; furthermore, Applicant has not demonstrated that the claimed ration renders unexpected results.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Double Patenting

18. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

19. Claims 1-15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of copending Application No. 10/883834. The claims in the instant application are identical to that present in 10/883834. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

20. The rejection of claims 1-15, provisionally rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of 10/262164, U.S. PreGrant Pub No. 20030211465, is withdrawn in view of the amendment made to the claims in 10/262164, i.e., cancellation of claim 12.

Conclusion

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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